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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,897	06/08/2006	Stephen Ray	CARP-0120	7221

23377 7590 01/10/2008
WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
01/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,897	RAY, STEPHEN	
	Examiner	Art Unit	
	Maria Leavitt	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32,37-42,44 and 46-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32, 37-42, 44, 46-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Claims 1, 2--32 and 44, 47 and 48 drawn to cells and to **an *in vivo*** method of inducing totipotent or pluripotent stem cells which comprises providing isolated RNA to **a cell population in a patient** under conditions to induce differentiation of said stem cells.

II. Claims 1, 3-9, 15-18, **19--32**, 44, 47, and 48 drawn to cells and to **an *in vitro*** method of inducing totipotent or pluripotent stem cells which comprises providing isolated RNA to **a cell culture** of **said stem cells** under conditions to induce differentiation of said stem cells.

III. Claims 37-41 and 49 drawn to cells and to **an *in vitro*** method of reversing the differentiation of differentiated cells to produce a desired totipotent or pluripotent stem cells comprising providing isolated RNA to **a cell culture of said differentiated cells** under conditions to induce differentiation of said differentiated cells into stem cells.

IV. Claims 42, 50 and 51 drawn to cells and to **an *in vitro*** method of producing differentiated cells which comprises: (i) providing isolated RNA to **a cell culture of differentiated cells** under conditions to induce differentiation of said differentiated cells into stem cells and (ii) providing isolated RNA to **a cell culture** of **said stem cells** under conditions to induce differentiation of said stem cells.

V. Claims 46 are drawn to a method of **screening for an RNA sequence** comprising extracting RNA from cells, separating the extracting RNA into fractions, providing a fraction to a test cell, and analyzing the test cell for an altered property.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

37 CFR 1.475 (c) states:

"If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present"

37 CFR 1.475 (d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)".

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking groups I-V appears to be that they all relate to methods and cells wherein the alteration of cell properties is desired comprising providing isolated RNA comprising a RNA sequence extractable from cells comprising the desired cell type(s) to a population of cells under conditions whereby the alteration of the cell property is achieved. However, prior art has taught induction of a T-cell specific antigen on bone marrow

lymphocytes following exposure to thymus RNA extract. complementary DNA by retrovirus mediated gene transfer into murine embryonic stem cells enhances erythropoiesis in differentiating embryoid bodies (Immunology, 1978, pp. 123-129). Therefore, the technical feature linking the invention of groups I-V does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

Inventions of **Group I drawn an *in vivo*** method of inducing pluripotent stem cells are structurally and functionally different from inventions of **Group II** drawn **to an *in vitro* method** of inducing pluripotent stem cells because they are methods drawn to materially different steps, having distinct physical properties and biological functions as the result of comprising administration of an isolated RNA to a cell population in a patient or to a cell population in culture, respectively. Hence, the information provided by a method of Group I comprises unique technical features that are not shared by the inventions of Groups II. For example, inventions of Group I require that the stem cells reside in the body of the patient in order to be exposed to the RNA in situ, which step is not required by the method of Group II. Moreover, inventions of **Group III drawn to** reversing the differentiation of differentiated cells to produce a desired totipotent or pluripotent stem cells includes unique technical features that are not shared by the inventions of Groups I or II. Additionally, Inventions of Group V are drawn to a method of **screening for an RNA sequence** including unique technical features that are not shared by the

inventions of Groups I, II III or IV. For example inventions of Group V require extracting RNA from cells comprising a desired cell type; separating the extracted RNA into different fractions; providing a fraction to one test cell analyzing the test cells for an altered property possessed by the desired cell type from which the RNA was extracted.The foregoing steps are not required by the methods of Groups I, II III or IV. Because these inventions are distinct for the reasons given above, and are separately classified and searched, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Species restriction

Should Groups **I** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

1) A genus of alteration of the cell property as recited in claims 10, 11, and 12 selected from one of the following:

A method that improves stem cell mediated repair in the patient, a method that induces stem cell mobilization, migration, integration, proliferation and/or differentiation in the patient, and a method that effects repair of diseased cells, alters the genetic constitution of cells, induces specific cell types and/or cell fates, changes the immunological profiles of cells, and/or induces particular desired immune functions or properties

The species are independent or distinct because there are cell properties having different chemical structures, physical properties, and biological functions. Thus, the combined features

of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 37, and 42 are generic.

Should Groups **I or II** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

2) A genus of alteration of the cell property as recited in claims 6, 7, 8, and 9 selected from one of the following:

the differentiation of a stem cell to an adult specialized cell, the reverse differentiation of an adult specialized cell to a stem cell, the differentiation of a specialized adult cell to an adult cell of a different specialty, and alteration of the cell property is a change in immunological profile.

The species are independent or distinct because there are cell properties having different chemical structures, physical properties, and biological functions. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 37, and 42 are generic.

3) A genus of RNA sequences that are extractable from cells as recited in claims 15, 16, 17 and 18 selected from one of the following:

from cells of a different developmental stage than the developmental stage of the cells to be treated, from cells of a more active cell generative stage than that of the cells to be treated, from an individual who shows immunity or resistance to a disease or condition and from foetal cells, neonatal cells, juvenile cells or embryonic stem cells.

The species are independent or distinct because there are RNA sequences that are extractable from cells having different chemical structures, physical properties, and biological functions. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 37, and 42 are generic.

If applicant elects RNA sequences that **are extractable from stem cells,** a further election of species is required from the following stem cells:

4) A genus of **stem cells** as recited in claims 23, 24 and 47 selected from one of the following:

(i) Adult animal stem cells: bone marrow stromal cells, hematopoietic stem cells or neuronal stem cells or a corresponding derived stem cell line, and

(ii) embryonic stem cells or a stem cell line derived from such cells.

The species are independent or distinct because there are stem cells having different chemical structures, physical properties, and biological functions. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 37, and 42 are generic.

Should Groups **III** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

5) A genus of differentiated cells as recited in claims 39 and 40 selected from one of the following:

skin cells, bone marrow cells and hematopoietic cells or a cell line derived from such cells, fibroblasts or a fibroblast cell line.

The species are independent or distinct because there are differentiated cells having different chemical structures, physical properties, and biological functions. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 37, and 42 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Maria Leavitt, PhD
Patent Examiner P/1633
Remsen 2B55

Phone: 571-272-1085

ANNE M. WEHBE
PRIMARY EXAMINER